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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PATRICIA A. KAVALIR,	)	
	)	Case No. 07 cv 0835
Plaintiff,	)	
	)	Judge John W. Darrah
v.	)	
MEDTRONIC, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

This matter is before the Court upon Defendant Medtronic, Inc.'s ("Medtronic") Motion to Dismiss Plaintiff's Second Amended Complaint. (Doc. No. 42.) For the reasons stated below, the motion is denied.

LEGAL STANDARD

Dismissal is warranted under Federal Rule of Civil Procedure 12(b)(6) if the factual allegations of the complaint, viewed in the light most favorable to the plaintiff, do not plausibly entitle the plaintiff to relief. *Bell Atlantic Corp v. Twombly*, __ U.S.__, 127 S. Ct. 1955, 1968-69 (2007). In considering a motion to dismiss under Rule 12(b)(6), all well-pleaded factual allegations are accepted as true and all reasonable inferences are construed in favor of the plaintiff. *Sprint Spectrum L.P. v. City of Carmel, Indiana*, 361 F.3d 998, 1001 (7th Cir. 2004). "A plaintiff's complaint need only provide a short and plain statement of the claim showing that the pleader is entitled to relief, sufficient to provide the defendant with fair notice of the claim and its basis." *Tamayo v.*

Blagojevich, __ F.3d __ (7th Cir. 2008), 2008 WL 2168638 (7th Cir. 2008) (internal quotations omitted). However, "it is not enough for a complaint to avoid foreclosing possible bases for relief; it must suggest that the plaintiff has a right to relief . . . by providing allegations that 'raise a right to relief above a speculative level.'" *EEOC v. Concentra Health Services, Inc.*, 496 F.3d 773, 777 (7th Cir. 2007) (citing *Bell Atlantic*, 127 S. Ct. at 1068-69). If the complaint fails to provide such allegations, "the plaintiff pleads itself out of court." *Id.*

BACKGROUND

The following facts are alleged in Plaintiff's Second Amended Complaint ("Complt."). In the spring of 2000, Plaintiff had surgery at MacNeal Memorial Hospital in Berwyn, Illinois, to remove a portion of her right breast due to cancer. Within a few weeks, she underwent more surgery to remove cancerous cells in her upper abdomen. Following the surgery, Plaintiff was given chemotherapy treatments, which she was unable to tolerate and which were discontinued before completion. The physicians who performed the cancer surgery and administered the chemotherapy treatments advised Plaintiff that the chemotherapy treatments had damaged her heart. Plaintiff engaged the services of physicians who specialized in treating patients with adverse heart conditions. Plaintiff's heart physicians advised her that she should have an Implantable Cardioverter Defribrillator Device ("ICD") and made arrangements for her to obtain an ICD at the University of Chicago Hospitals.

Plaintiff purchased an ICD from Medtronic, which was implanted in Plaintiff on July 27, 2000 (the 2000 ICD).[1] In the summer of 2001, the insulated lead wires forming a part of the 2000 ICD were surgically repositioned in Plaintiff's upper chest area instead of under her skin because her skin was determined to be too thin to secure the ICD. Later in 2001, or early 2002, Plaintiff underwent additional surgery to remove a large part of her left breast due to cancer.

In 2003, Plaintiff experienced frequent electrical shocks from the 2000 ICD. At this time, Plaintiff's heart physicians were associated with Loyola University Medical Center. Plaintiff was hospitalized at Loyola from May 9 through May 11, 2003, and the 2000 ICD was removed and replaced with another Medtronic ICD (the 2003 ICD).

On April 21, 2005, the 2003 ICD was replaced at Loyola with a new Medtronic ICD (the 2005 ICD).[2] In late June 2006, Plaintiff experienced a series of shocks from the 2005 ICD, which led to Plaintiff's emergency hospitalization. Plaintiff was diagnosed as suffering from a condition similar to traumatic shock syndrome, and it was determined that the 2005 ICD had failed. Difficult surgery to correct the deficiencies of the 2005 ICD was performed, and another ICD was implanted on July 3, 2006 (the 2006 ICD).

Plaintiff filed a lawsuit in state court on June 16, 2006, alleging strict liability and breach of warranty causes of action against Medtronic, Loyola and the University of

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[1] The Second Amended Complaint identifies the ICD implanted in Plaintiff on July 27, 2000 as a GEM 111VR Model 7231 ICD. (Complt., ¶ 9.)

[2] The Complaint does not provide an identification number for the 2005 ICD, but refers to an exhibit which cites an implant date of April 21, 2005 and an ICD Model No. 7278. (Complt., ¶ 17.)

Chicago Hospitals, arising from alleged defects in the 2000 and 2003 ICDs. Following motions to dismiss, the Circuit Court judge entered an order dismissing Plaintiff's action against Loyola and the University of Chicago Hospitals. (January 11, 2007 Order, attached to Def. Br. as Ex. B; hereafter, "January Order.") In addition, the judge granted Medtronic's motion to dismiss Plaintiff's strict liability claim arising from the 2000 ICD as barred by Illinois' two-year statute of limitations. The judge reasoned that Plaintiff alleged she was being shocked by the 2000 ICD as early as 2003 and was informed in May, 2003 that the insulation of the wires leading into the heart had become detached and were causing the shocks. The court found, based on these allegations, that a reasonable person should have known in 2003 that the injury was wrongfully caused. (January Order, p. 3.)

On February 12, 2007, Medtronic filed a notice of removal in this Court. Subsequently, pursuant to order of the Judicial Panel on Multidistrict Litigation, the case was transferred to the District of Minnesota for consideration in connection with multidistrict litigation pertaining to Medtronic ICDs. Following consolidated pretrial proceedings in the multidistrict litigation, Plaintiff and Medtronic settled claims related to the 2003 ICD. On March 24, 2008, Plaintiff's remaining claims were remanded to this Court.

Plaintiff alleges strict liability and breach of warranty claims arising from the 2000 and 2005 ICDs. Count I of the Complaint alleges strict liability for the 2000 ICD. Count II alleges strict liability for the 2005 ICD. Count III alleges a claim for breach of warranty. Count IV alleges a claim for breach of implied warranty.

ANALYSIS

Medtronic moves to dismiss all of Plaintiff's claims. First, Medtronic contends, Plaintiff's strict liability claim relating to the 2000 ICD was previously dismissed with prejudice by the Cook County Circuit Court and is, therefore, barred under the doctrine of *res judicata*.

As noted above, the Circuit Court issued an order granting Medtronic's motion to dismiss Plaintiff's strict liability claim on the basis of the statute of limitations. However, Medtronic's motion to dismiss was denied in other respects, and the order did not state it was final and appealable as to Medtronic. (*See* January Order, p. 4.)[3] Furthermore, as Plaintiff points out, on February 7, 2007, she filed a timely motion in the Circuit Court for, among other things, reconsideration of the statute-of-limitations ruling. (*See* Pltf. Br., Ex. 1.) After the motion for reconsideration was filed, but before it was ruled upon, Medtronic removed the action to federal court. On February 20, 2007, the Circuit Court entered and continued Plaintiff's motion for reconsideration "generally subject to further order of the District Court." (Pltf. Br., Ex. 2.) This scenario demonstrates that the January Order did not become final as to Medtronic. Therefore, the Circuit Court's ruling that Plaintiff's strict liability claim was barred by the two-year statute of limitations is not *res judicata* here. *See 4901 Corporation v. Town of Cicero*, 220 F.3d 522 (7th Cir. 2000) (in order for *res judicata* to apply, there must be a final

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[3] In contrast, the January Order clearly states that it is "Final and Appealable" as to the hospital defendants. (*See* January Order, p. 4.)

judgment on the merits).[4]

Medtronic also argues that all of Plaintiff's state-law claims are barred because the ICDs at issue have been approved by the Food and Drug Administration ("FDA") under its premarket approval process; therefore, Plaintiff's claims are preempted by the Medical Device Amendments of 1976 ("MDA").

The MDA established a regulatory scheme with various levels of FDA oversight for medical devices, depending on the risks they present. The most extensive oversight pertains to Class III devices that must undergo an extensive premarket approval process. These devices may enter the market only after the FDA reviews what is typically a multivolume application concerning a device's design, labeling and manufacturing specifications and determines that the specifications provide a reasonable assurance of the safety and effectiveness of the product. Once a device is approved by the FDA under this process, no changes affecting safety or effectiveness may be made to the device unless permission is obtained from the FDA.

Further, the MDA contains an express preemption clause, which states:

> (a) General Rule
>
> Except as provided in subsection (b) of this section, no State . . . may establish or continue in effect with respect to a device intended for human use any requirement –

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[4] Medtronic concedes in its reply that *res judicata* is not a proper basis upon which to dismiss Count I but raises for the first time the argument that the claim should be dismissed because the state court's ruling is law of the case. This may well be true, but the Court will not entertain new legal arguments made for the first time in a reply brief to which Plaintiff had no opportunity to respond.

> (1) which is different from, or in addition to, any requirement applicable under [federal law] to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has held that this preemption clause bars state-law claims challenging the safety and effectiveness of a medical device marketed in a form that received premarket approval from the FDA. *Riegel v. Medtronic, Inc.*, __ U.S. __, 128 S.Ct. 999, 1001 (2008) (finding New York common-law claims of negligence, strict liability and implied warranty arising from injuries sustained from defendant's balloon catheter preempted by MDA).

In *Riegel*, the Court held that the preemption question consists of a two-part analysis. First, the court must determine whether "the Federal Government has established requirements applicable to [the medical device]." *Riegel*, 128 S. Ct. at 1006. If so, the court must determine whether the state-law requirements with respect to the device are "different from, or in addition to" the federal requirements. *Id.* If both of these conditions are met, the state-law requirements, or claims, are preempted.

Relying on *Riegel*, Medtronic argues that both conditions for preemption are satisfied with respect to Plaintiff's alleged state-law claims. Medtronic asserts "there can be no dispute that since Medtronic marketed the Model 7231 and Model 7278 under valid premarket approvals, they were subject to the 'requirements' imposed by those approvals." (Def. Br. at 9.) As support for this assertion, Medtronic relies solely on information obtained from the FDA's website and attached as Exhibit D to its brief.

Medtronic contends these pages show that the 2000 and 2005 ICDs obtained FDA premarket approval. Medtronic contends Plaintiff's claims are preempted on the basis that the "common thread" of Plaintiff's claims is that the ICDs sold by Medtronic were unsafe, unmerchantable and unfit for their intended use, and the manufacture and design of the ICDs were submitted for FDA approval. (Def. Br. at 10-11.)

Plaintiff makes several arguments in opposition to Medtronic's position. Plaintiff points out that none of the documents attached as Exhibit D to Medtronic's brief refers to the devices identified in the Second Amended Complaint, a GEM IIIVR Model 7231 or PRM 112 995 H Model 7278, or to the lead wires used to implant the ICDs in Plaintiff, the part Plaintiff contends caused her injuries. Plaintiff notes that several exceptions to the premarket approval process were recognized by the Supreme Court in *Riegel*, namely, pre-1976 devices that were already on the market and were allowed to remain on the market without approval pursuant to a "grandfather" provision and devices that are "substantially equivalent" to pre-existing devices. (Plaintiff Br. at 11.) Plaintiff states the FDA's internet pages attached to Medtronic's brief do not demonstrate that the ICDs and ICD leads identified in the Complaint received premarket approval or were approved as substantial equivalents.

The Court agrees that the FDA internet pages attached to Medtronic's brief do not provide a sufficient basis for the Court to determine, at this stage of the proceeding, that Plaintiff's state-law claims are preempted under *Riegel*. The pages do not on their face make clear what specific form or forms of Medtronic's ICDs received premarket approval and whether those are the same ICDs as those implanted in Plaintiff in 2000 and

2005. Furthermore, at this stage, the Court cannot determine whether potential issues may exist as to whether some of Plaintiff's state-law claims are "different from" or "in addition to" those required by the FDA. *See, e.g, Riegel*, 128 S. Ct. at 1011 (recognizing that state regulations that are parallel, not "different from" or "in addition to" federal requirements, are not preempted under the MDA.)[5]

CONCLUSION

For the reasons stated above, Defendant's Motion to Dismiss Plaintiff's Second Amended Complaint (Doc. No. 42) is denied.

Date August 27, 2008

John W. Darrah
United States District Court Judge

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[5] Medtronic asserts there may have been some confusion as to the FDA's premarket approval website pages, and submits with its reply additional web page information from the FDA and a declaration of Jose A. Isasi, stating how the pages were derived and what they represent. (Ex. 2 to Medtronic's Reply Mem.) Medtronic urges the Court simply to take judicial notice that these pages establish that the ICDs at issue received premarket approval, and, therefore, Plaintiff's state-law claims are preempted. As discussed above, however, the Court cannot determine simply from the face of the web pages that the preemption requirements set forth in *Riegel* are satisfied with respect to all of Plaintiff's claims. Furthermore, the Court will not consider evidence outside of the pleadings in determining this motion to dismiss.